UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/601,371	12/05/2000	Tsukasa Seya	49927	2244

7590 11/15/2001

Dike Bronstein Roberts & Cushman
Intellectual Property Practice Group
Edward & Angell
P O Box 9169
Boston, MA 02209

EXAMINER
PRASAD, SARADA C

ART UNIT	PAPER NUMBER
1646	19

DATE MAILED: 11/15/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/601,371	SEYA ET AL.	
	Examiner	Art Unit	
	Sarada C Prasad	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 September 2001* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

Application/Control Number: 09/601,371

Art Unit: 1646

Detailed Action

1. Receipt of Applicants' arguments and amendments filed in Paper No. 10(9/17/01) is acknowledged. Currently, claims 1-10 are under consideration.

2. The following previous rejections and objections are withdrawn in light of Applicants' amendments filed in Paper No.10 (9/17/01).

(i) the objection to specification based on polynucleotide sequences and CRF to comply with the sequence rules;

(ii) the objection to specification based on

recitation of claim to priority,

reference to prior application, and

recitation of almost in page 1, 2nd para, lines 6-8;

(iii) the rejection of claims 9, 10, as improper process claims, under 35 USC 101, based on recitation of 'use of …';

(vi) the rejection of claims 1-2, 9-10 under 35 U.S.C. 112-second paragraph based on recitation of acronyms for example: M161Ag, several different cytokines, INF-γ instead of IFN-γ; and the rejection based on recitation of 'use of protein M161Ag or gene recombination products thereof'.

3. Applicant's arguments filed in Paper No. 10, 9/17/01, have been fully considered but were deemed persuasive in part. The issues remaining and new issues, are stated below.

4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112 first paragraph

5. Claims 1-10 are rejected under 35 USC § 112 first paragraph in Paper No. 6 (3/14/01).

5a. This rejection of record is being maintained for reasons of record set forth in pages 3-4 (based on lack of enabling written description) of the previous office action in Paper No. 6 (3/14/01).

Receipt of the CRF and sequence listing in response to the previous action is acknowledged. However, claims 1, 6-10 recite 'cytokine inducers and treatment agents comprising a protein of Mycoplasma fermentans M161Ag or gene recombination products thereof'. The isolated polynucleic acid has not been referenced in the claims with a SEQ ID No. nor has the instant polynucleotide/polypeptide been specifically described in the disclosure to be represented by SEQ ID No as per the written description guidelines. In order to comply with written description guidelines, the Applicants need to provide SEQ ID description in the specification, recite the use of it in the claims for the intended purpose, in addition of providing a CRF and sequence listing. As mentioned in the previous office action, knowledge of the polynulceotide sequence of the encoded protein M161Ag does not allow one of skill in the art to envision and make the polypeptide M161Ag and use it for immunomodulation or treatment of immunological diseases.

Therefore, the rejection of claims 1-10 based on insufficient written description is maintained.

5b. Claims 1-10 are rejected under 35 USC 112-first paragraph based on scope of enablement in Paper No. 6 (3/14/01).

This rejection of record is being maintained for reasons of record set forth in pages 5-6 (induction of 'all cytokines'), and 6-7 (treatment of 'all immunological diseases') (Paper No. 6, 3/14/01).

The rejection is based on the fact that the specification is enabled for induction of IL-β , TNF-α, IL-6, IL-10, IL-12, and IFN-γ and not 'all other' cytokines by the Mycoplasma fermentans M161Ag, and the specification is also not enabled for remedy, or therapy, or treatment of 'any' immunological diseases or immunomodulation that is beneficial to subjects in need of cytokines termed 'cytokine deficiency'. The specification has not addressed remedy of or treatment of any immunological diseases. Based on the disclosure, and the broad scope of instant claims, two grounds of scope of enablement rejection have been established, namely (i) the fungal antigen M161Ag can induce a group of cytokines, listed as IL-β , TNF-α, IL-6, IL-10, IL-12, and IFN-γ, and 'not all other cytokines', and (ii) the specification is not enabled for use of these induced groups of cytokines as immunomodulators or treatment agents for 'any' immunological diseases.

Applicants have assumed that the instant 'cytokine inducer M161Ag' can be used for therapeutic purposes in immunological diseases that require 'cytokine administration'. Instant cytokines IL-β , TNF-α, IL-6, IL-10, IL-12, and IFN-γ do not comprise an exhaustive list of all the cytokines discovered so far, or to be discovered. Based on predictability in the art, it is also not feasible to induce any group of cytokines that such fungal antigens can stimulate to achieve results in the form of treatment of unnamed immunological diseases. The specification

fails to point to any one diseases in particular, nor successful treatment. The examples disclose *in vitro* cell based studies to elicit expected *in vivo* responses characteristic of cytokine induction upon treatment with M161Ag, for example, incubation of purified peripheral blood monocytes with M161Ag and assay of IL-10 and IL-12 produced. That is hardly the case while injecting a fungal antigen such as M161Ag that elicits a complex response of stimulating innate immune system, which is not guaranteed to direct therapeutic responses in subjects termed as being in need of cytokine therapy 'in general'.

It is evident from the specification, that none of the diseases symptoms to be treated, or the subjects that require cytokine administration, or what are the cytokines required for the said subjects that exhibit symptoms of cytokine deficiency are disclosed. The instant claims are extremely broad in recitation of 'cytokine inducers' and 'cytokine inducers are used as immunomodulators'. Based on the limited guidance provided, one of skill in the art is required to test the parameters for any therapeutic use of instant M161Ag both for cytokine induction as to which cytokines are induced and for therapeutic modality to decide which of the induced cytokines are useful for instantly claimed immunomodulation. Such guidance has to be established in each and every one of the unnamed immunological diseases. It would be undue experimentation for a skilled artisan to practice the invention as claimed without guidance. The applicants are asking for a license to perform further experimentation. Each of the cytokines has distinct properties as alluded to in the previous office action.

Applicants' provided IDS directing the Examiner to take note of the use of M161 Ag for therapeutic purposes 'Role of Toll-like receptors for Innate Immune therapy of cancer' has not been received, however Examiner's review of such literature points to extensive research activity

on this topic. The instant rejection is based on the broad scope of claims, and possible evidence of the use of 'specific cytokine inducers' for treatment of 'specific immunological diseases' is not disputed.

Therefore, the rejection of record is maintained.

Conclusion

6. No claims are allowable.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sarada C Prasad whose telephone number is 703-305-1009. The examiner can normally be reached Monday – Friday from 8.00 AM to 4.30 PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (703) 308-6564. The fax phone number for the organization where this application or proceeding is assigned is 703-308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Sarada Prasad, Ph.D.
Examiner
Art Unit 1646
November 12th , 2001

Prema Mertz
PREMA MERTZ
PRIMARY EXAMINER